ITO CO.,LTD. *established in 1916*

3-3-3 TOYOTAMA-MINAMI, NERIMA-KU, TOKYO
176-0014 JAPAN

TEL:81-3-3994-8996
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K112520

OCT 2 6 2011

510(k) Summary

US-101L, US-103S

Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

Submitter Name: ITO CO., LTD.
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Contact Name: Haruhisa Okada

Data Prepared June, 9 2011

Proprietary Name: US-101L, US-103S
Common Name: diathermy, ultrasonic, for use in applying therapeutic deep heat
Class: II
Predicate Device: K032793- US-100 Ultrasound Therapy Unit
: K024307- Dermosonic Non-Invasive Subdermal Therapy Systemt

Device Description:

US-101L, US-103S are portable type ultrasound therapy units with built in ultrasound transducer. Ultrasound head (probe) is integral with the main body. Two sizes, US-101L (L size) for 1MHz and US-103S (S size) for 3MHz are available. In the output mode, continuous output (100%) or pulsed output (50%, 40%, 30%, 20%, 10%, 5%) are used. These units are intended to treat the affected area by applying the treatment head to skin.

The proposed devices have incorporated similar features as the predicate devices such as the main ultrasound output specification and safety functions.

Detailed comparison of specific US-101L, US-103S features and characteristics to the predicate devices is contained in Section 11, Executive Summary Substantial Equivalence Discussion.

Indications for Use:

The US-101L, US-103S are indicated for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions, including relief of pain, muscle spasms, and joint contractures.

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Cited Standards to Determine Substantially Equivalence:

US-101L, US-103S comply with FDA recognized IEC 60601-1, IEC60601-1-2 and IEC60601-2-5.

Non-clinical Testing:

Non-clinical verification and validation testing was conducted on US-101L, US-103S devices, and the results of such testing appear in Section 15 of this submission.

Truthful and Accuracy Statement:

Singed by a corporate management representative of the submitter, the required statement attesting to the truthfulness and accuracy of the information contained in Section 6 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 6 2011

Ito Co., Ltd.
% TÜV SÜD America, Inc.
Mr. Alexander Schapovalov
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K112520
Trade/Device Name: US-101L, US-103S
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI
Dated: October 17, 2011
Received: October 19, 2011

Dear Mr. Schapovalov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K112520

Device name: US-101L, US-103S

Indications for Use:

The US-101L, US-103S are indicated for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions, including relief of pain, muscle spasms, and joint contractures.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112520

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)